

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ALABAMA  
SOUTHERN DIVISION**

PENNY SIMPSON, an Alabama resident; )  
Plaintiff, )  
v. )  
BAYER CORPORATION, an Indiana )  
corporation; BAYER HEALTHCARE )  
PHARMACEUTICALS INC., a Delaware )  
corporation; BAYER HEALTHCARE, )  
LLC, a Delaware limited liability company, )  
BERLEX LABORATORIES )  
INTERNATIONAL, INC., a Delaware )  
corporation;  
Defendants. )

Civil Action Number \_\_\_\_\_  
**JURY TRIAL DEMANDED**

**COMPLAINT**

1. This is an action for strict products liability, breach of express and implied warranty, negligence, negligence per se, fraudulent suppression, fraudulent misrepresentation, fraud, and negligent misrepresentation brought by Plaintiff for damages associated with Plaintiff PENNY SIMPSON's (hereinafter, singularly, "Plaintiff") ingestion of the pharmaceutical drug Yasmin (drospirenone and ethinyl estradiol) (hereinafter, "Yasmin"), an oral contraceptive designed, manufactured, marketed, and distributed by Defendants. As a result of the ingestion of the pharmaceutical drug Yasmin, Plaintiff has suffered injuries to her person including, but not limited, to pulmonary embolisms.

**Jurisdiction and Venue**

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332, because complete diversity exists and the amount in controversy exceeds \$75,000 exclusive of interest and costs.

3. The Court has personal jurisdiction over the defendants to this action because they possess the requisite minimum contacts with the forum.

4. Venue is proper in this district pursuant to 28 U.S.C. § 1391, et seq.

**Parties**

5. Plaintiff PENNY SIMPSON, at all times relevant and material, is a citizen of Alabama and over the age of nineteen.

6. Plaintiff PENNY SIMPSON was provided and ingested Yasmin, and as a result suffered severe injuries and other damages, including but not limited to blood clots and pulmonary embolisms in her right leg, left arm and both lungs.

7. Defendant BAYER CORPORATION is an Indiana corporation, with its principal place of business at **100 Bayer Road, Pittsburgh, Pennsylvania 15205**. BAYER CORPORATION researched, developed, manufactured and marketed Yasmin at all times relevant. At all relevant times, BAYER CORPORATION conducted substantial business in the state of Alabama by selling and distributing its products in Alabama, and engaged in substantial business in Jefferson County, Alabama.

8. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is a Delaware corporation with its principal place of business at **6 West Belt Road, Wayne, New Jersey 07040**. BAYER HEALTHCARE PHARMACEUTICALS, INC., upon information and belief, was created by the integration of Bayer Healthcare and Berlex Laboratories. BAYER

HEALTHCARE PHARMACEUTICALS, INC., researches, develops, manufactures and markets pharmaceutical products including Yasmin. At all relevant times, BAYER HEALTHCARE PHARMACEUTICALS, INC., conducted substantial business in the state of Alabama by selling and distributing its products in Alabama.

9. Defendant BAYER HEALTHCARE, LLC, is a Delaware corporation whose principal place of business is at **555 White Plains Road, Tarrytown, New York 10591**. BAYER HEALTHCARE LLC was involved in the integration of Bayer Healthcare and Berlex Laboratories. BAYER HEALTHCARE LLC, researches, develops, manufactures, and markets pharmaceutical products, including Yasmin. At all times relevant and material, Defendant BAYER HEALTHCARE, LLC, engaged in substantial commerce in the state of Alabama by distributing its products in Alabama.

10. Defendant BERLEX LABORATORIES INTERNATIONAL, INC., is a Delaware corporation whose principal place of business is at Montville, New Jersey. BERLEX LABORATORIES INTERNATIONAL INC. was integrated with Bayer Healthcare leading to the formation of Bayer Healthcare Pharmaceuticals, Inc. BERLEX LABORATORIES INTERNATIONAL INC was involved in the research, development, manufacturing, and marketing of the pharmaceutical product Yasmin, At all times relevant, BERLEX LABORATORIES INTERNATIONAL INC conducted regular and substantial commerce and business activity in Alabama by selling their goods in the state.

11. Defendants BAYER CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER HEALTHCARE, LLC are collectively referred to herein as “Bayer” and refers to any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and

assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

12. At all times relevant and alleged herein, Bayer included and includes any and all parents, subsidiaries, affiliates, franchises, partners, joint ventures, and organizational units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives, and any and all kinds of other persons acting on their behalf.

13. As used herein, "Defendants" includes all named Defendants.

14. Defendants, either directly, or through their agents, apparent agents, servants, or employees, at all relevant times, sold or distributed Yasmin in the State of Alabama, as well as other states and foreign countries.

15. Defendants derive a substantial portion of their revenues from sales of their pharmaceutical products in the state of Alabama.

16. Defendants expected or should have expected that their business activities could or would have consequences within the state of Alabama, as well as throughout the United States.

#### **FACTUAL BACKGROUND**

17. At all times relevant, Defendants designed, manufactured, marketed, and distributed Yasmin.

18. Yasmin, known generically as drospirenone and ethinyl estradiol, is a combination birth control pill containing the hormones estrogen and progestin and was approved by the FDA in April 2001. In the case of Yasmin, the estrogen is ethinyl estradiol and the progestin is drospirenone.

19. Yasmin is indicated for the prevention of pregnancy in women who elect to use an oral contraceptive.

20. The difference between Yasmin and other birth control pills on the market is that drospirenone has never before been marketed in the United States and is unlike other progestins available in the United States.

21. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

22. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism, where Yasmin was suspected as the cause, including two deaths.

23. Defendants have twice been warned by the FDA, in 2003 and 2008, for misleading the public through the use of television ads which overstate the efficacy of Yasmin and minimize serious risks associated with the drug.

24. The use of Yasmin has a prothrombotic effect resulting in thrombosis such as the pulmonary embolisms suffered by the Plaintiff.

25. Defendants failed or neglected to recognize the correlation between the use of Yasmin and increased thrombosis formation despite the wealth of scientific information available.

26. Upon information and belief, Defendants knew or should have known about the correlation between Yasmin use and a prothrombotic effect and still promoted, sold, advertised, and marketed the use of Yasmin.

27. As a result of the manufacture, marketing, advertising, promotion, distribution and/or sale of Yasmin to Plaintiff herein, Plaintiff was prescribed with and ingested Yasmin, sustaining severe and permanent personal injuries, to wit: pulmonary embolism and all resulting damages, including the potential for future thrombembolic events.

**FIRST CAUSE OF ACTION  
(Negligence and Negligence Per Se)**

28. Plaintiff restates the allegations set forth above as if fully rewritten herein.

29. Defendants, directly or indirectly, negligently and/or defectively designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed Yasmin.

30. At all times material hereto, Defendants had a duty to users and/or consumers of Yasmin, including Plaintiff, to exercise reasonable care in the design, testing, inspection, manufacture, assembly, development, labeling, sterilization, licensing, marketing, advertising, promotion, sale, packaging, supply and/or distribution of Yasmin.

31. Defendants breached that duty and were negligent in the design, testing, inspection, manufacture, assembly, development, labeling, sterilization, licensing, marketing, advertising, promotion, sale, packaging, supply and/or distribution of Yasmin in that: Yasmin was defective when put on the market by Defendants; that with such defect, Yasmin was reasonably certain to be dangerous when put to normal use; and that Defendants failed to use reasonable care in designing or making Yasmin or in inspecting it for defects. Specifically, Defendants breached their duty by, among other things:

- a. Failing to include adequate warnings that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, to the potential risks and serious side effects of the drug;
- b. Failing to adequately and properly test and inspect the drug before placing the drug on the market;
- c. Failing to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious side effects, including but not limited to, pulmonary embolus, deep venous thrombosis and/or death and other serious and life threatening side effects;
- d. Failing to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and other serious side effects associated with the drug, including, among other things, pulmonary embolus, deep venous thrombosis and/or death and other serious and life threatening side effects;
- e. Failing to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks associated with the use of the drug;
- f. Failing to recall and/or remove the drug from the stream of commerce despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug; and

g. Encouraging misuse and overuse while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiff, in order to maximize profit from sales.

32. Defendants knew or should have known that Yasmin caused unreasonably dangerous risks and serious side effects of which users and/or consumers of the drug, including Plaintiff, were not aware. Defendants nevertheless advertised, promoted, marketed, sold, distributed and/or supplied Yasmin knowing that there were safer methods for contraception.

33. By reason of the foregoing, Plaintiff experienced and is at continued risk of experiencing serious and life-threatening side effects including but not limited to, pulmonary emboli, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

34. By reason of the foregoing, Plaintiff was damaged by the negligence and wanton and willful recklessness of the Defendants.

35. As a direct, legal, proximate and producing result of the negligence of defendants, Plaintiff sustained injuries as set forth above.

36. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. The Plaintiff is informed and believes and further alleges that she will in the future be required to obtain further medical and/or hospital care, attention, and services.

**SECOND CAUSE OF ACTION**  
**(Strict Products Liability - Unreasonably Dangerous Design)**

37. Plaintiff restates the allegations set forth above as if fully rewritten herein.
38. At all times material hereto, Defendants have engaged in the business of designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing the drug Yasmin, which is defective and unreasonably dangerous to users and/or consumers of the drug, including Plaintiff.
39. At all times material hereto, Yasmin was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a defective and unreasonably dangerous condition in ways which include, but are not limited to, one or more of the following:
- a. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe and fit for its intended use or reasonably foreseeable purpose or as intended to be used, thereby subjecting users and/or consumers of the drug, including Plaintiff, to risks which exceeded the benefits of the drug;
  - b. The drug was insufficiently tested;
  - c. The drug caused harmful side effects that outweighed any potential utility;
  - d. The drug was not accompanied by adequate labeling or instructions for use to fully apprise the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and serious side effects associated with its use;

e. In light of the potential and actual risk of harm associated with the drug's use, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that Yasmin should not have been marketed in that condition.

40. At all times the drug Yasmin was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed, it was expected to reach, and did reach, users and/or consumers of the drug across the United States, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was sold.

41. At all times, Plaintiff used Yasmin (drospirenone and ethinyl estradiol) for its intended or reasonably foreseeable purpose.

42. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Yasmin, Plaintiff sustained injuries as set forth above.

**THIRD CAUSE OF ACTION  
(Strict Products Liability - Failure to Warn)**

43. Plaintiff restates the allegations set forth above as if fully rewritten herein.

44. Yasmin was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, to the dangerous risks and reactions associated with Yasmin when used for its intended or reasonably foreseeable purpose. Those dangerous risks and reactions included, but were not limited to, pulmonary embolisms, deep venous thrombosis and/or death and other serious and life threatening side effects.

45. At all times, Plaintiff used the drug for its intended or reasonably foreseeable purpose.

46. Plaintiff could not have discovered any defect in the drug through the exercise of care.

47. Defendants, as manufacturers of a prescription drug, are held to the level of knowledge of an expert in the field.

48. The warnings that were given by Defendants were not accurate or clear and/or were ambiguous.

49. Defendants had a continuing duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of Yasmin, including Plaintiff, of the potential risks and serious side effects associated with the use of the drug.

50. As a direct, legal, proximate and producing result of Defendants' failure to warn, Plaintiff sustained injuries as set forth above.

#### **FOURTH CAUSE OF ACTION (Breach of Express Warranty)**

51. Plaintiff restates the allegations set forth above as if fully rewritten herein.

52. Defendants made express representations to the consuming public at large through their aggressive marketing and advertising campaigns relative to their product, Yasmin.

53. Defendants, through their detail sales representatives, made representations of the safety and efficacy of their product, Yasmin.

54. Yasmin does not conform to the express representations made through Defendants' advertising and marketing efforts.

55. Yasmin does not conform to the express representations made by Defendants' agents/sales representatives.

56. Defendants' conduct in this matter was a contributing cause of injuries and damages suffered by plaintiff.

**FIFTH CAUSE OF ACTION  
(Breach of Implied Warranties)**

57. Plaintiff restates the allegations set forth above as if fully rewritten herein.

58. At the time that Defendants designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed the drug Yasmin, Defendants knew of the intended, reasonably foreseeable and/or ordinary use of Yasmin and impliedly warranted the drug to be of merchantable quality and safe and fit for such use.

59. Plaintiff, in ingesting Yasmin, reasonably relied upon the skill and judgment of Defendants as to whether Yasmin was of merchantable quality and safe and fit for its intended, reasonably foreseeable and/or ordinary use.

60. In breach of the implied warranty given by Defendants, Yasmin was not of merchantable quality or safe or fit for its intended, reasonably foreseeable and/or ordinary use because the product was unmerchantable; in a defective condition; unreasonably dangerous; and unfit for the intended, reasonably foreseeable and/or ordinary purpose for which it was intended as described above.

61. In breach of the implied warranty given by Defendants, Yasmin was not of merchantable quality or safe or fit for its intended, reasonably foreseeable and/or ordinary use because, among other things:

- a. Use of Yasmin carried a risk of, among other things, pulmonary embolus, deep venous thrombosis and/or death and other serious and life threatening side effects;

- b. Defendants failed to include adequate warnings with the drug that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and serious side effects of the drug; and
- c. Defendants failed to provide adequate post-marketing warnings or instructions after defendants knew or should have known of the potential risks and serious side effects associated with the use of the drug.

62. As a direct, legal, proximate and producing result of defendants' breach of warranty, Plaintiff sustained injuries as set forth above.

**SIXTH CAUSE OF ACTION  
(Fraudulent Misrepresentation)**

- 63. Plaintiff restates the allegations set forth above as if fully rewritten herein.
- 64. The Defendants falsely and fraudulently represented to the medical and healthcare community and to Plaintiff and the FDA, and the public in general, that Yasmin had been tested and was found to be safe and/or effective for its indicated use.
- 65. Said representations made by Defendants were, in fact, false.
- 66. When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.
- 67. These representations were made by Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and/or purchase Yasmin for

use, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

68. At the time the aforesaid representations were made by the Defendants and, at the time Plaintiff ingested Yasmin, Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

69. In reliance upon said representations, Plaintiff was induced to and did use Yasmin, thereby sustaining severe and permanent personal injuries, and is at an increased risk of sustaining severe and permanent personal injuries in the future.

70. Defendants knew and were aware or should have been aware that Yasmin had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and sufficient warnings.

71. Defendants knew or should have known that Yasmin had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

72. Defendants brought Yasmin to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

73. By reason of the foregoing, Plaintiff experienced and is at risk of experiencing serious and life-threatening side effects including but not limited to, pulmonary emboli, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

74. As a result of the foregoing acts and omissions, Plaintiff required, requires and will require more health care and services and did and will incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

**SEVENTH CAUSE OF THE ACTION  
(Fraudulent Concealment)**

75. Plaintiff restates the allegations set forth above as if fully rewritten herein.

76. At all times during the course of dealing between Defendants and Plaintiff and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Yasmin.

77. Defendants knew or were reckless in not knowing that its representations were false.

78. In representations to Plaintiff and/or Plaintiff's healthcare providers and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

- a. That Yasmin is not as safe as other available similar type drugs;
- b. That the risks of adverse events with Yasmin (drospirenone and ethinyl estradiol) were higher than those with other available similar type drugs;
- c. That the risks of adverse events with Yasmin were not adequately tested and/or known by Defendants;
- d. Plaintiff was put at risk of experiencing serious and dangerous side effects including but not limited to, pulmonary emboli, as well as other severe and

personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish;

- e. That patients needed to be monitored more regularly than normal while using Yasmin;
- f. That Yasmin was manufactured, marketed, produced, and distributed negligently;
- g. That Yasmin was manufactured, marketed, produced, and distributed defectively;
- h. That Yasmin was manufactured, marketed, produced, and distributed improperly;
- i. That Yasmin was designed negligently;
- h. That Yasmin was designed defectively; and
- j. That Yasmin was designed improperly.

79. Defendants were under a duty to disclose to Plaintiff and/or her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Yasmin.

80. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Yasmin, including the Plaintiff in particular.

81. Defendants' concealment and omissions of material facts concerning, *inter alia*, the safety of the use of Yasmin was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and/or her physicians, hospitals and/or healthcare providers into reliance, continued use of Yasmin, and actions thereon, and to cause them to purchase, recommend, and/or dispense Yasmin and/or use the drug.

82. Defendants knew that Plaintiff and/or her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Yasmin, as set forth herein.

83. Plaintiff, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

84. By reason of the foregoing, Plaintiff experienced and is at risk of experiencing serious and life-threatening side effects including but not limited to, pulmonary emboli, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

85. As a result of the foregoing acts and omissions Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

**EIGHTH CAUSE OF ACTION.  
(Negligent Misrepresentation)**

86. Plaintiff restates the allegations set forth above as if fully rewritten herein.

87. Defendants represented to the medical and healthcare community, and to the Plaintiff, the FDA and/or the public in general that Yasmin had been tested and found to be safe and effective for its intended use.

88. Those representations made by Defendants were, in fact, false.

89. Defendants failed to exercise ordinary care in the representation of Yasmin, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution into interstate commerce in that the Defendants negligently misrepresented Yasmin's high risk of unreasonable, dangerous side effects.

90. Defendants breached their duty in representing Yasmin's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and/or the public in general.

91. By reason of the foregoing, Plaintiff experienced and is at risk of experiencing serious and life-threatening side effects including but not limited to, pulmonary emboli, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

92. As a result of the foregoing acts and omissions Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

**NINTH CAUSE OF ACTION  
(Fraud and Deceit)**

93. Plaintiff restates the allegations set forth above as if fully rewritten herein.

94. Defendants recklessly, knowingly, intentionally, and fraudulently misrepresented to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, the safety and efficacy of the drug and/or recklessly, knowingly, intentionally and fraudulently concealed from the medical, pharmaceutical and/or scientific

communities, and users and/or consumers of the drug, including Plaintiff, material, adverse information regarding the safety and efficacy of Yasmin.

95. Defendants' misrepresentations were communicated to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, with the intent that they reach users and/or consumers of the drug, including Plaintiff.

96. Defendants either knew or should have known that the representations were false.

97. Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of the drug with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, would rely on such in selecting Yasmin.

98. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin in its labeling, advertising, product inserts, promotional materials or other marketing efforts.

99. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or should have known that its drug product had defects, dangers and characteristics that were other than what Defendants had represented to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff. Specifically, Defendants misrepresented to and/or actively concealed from the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, that:

- a. There had been insufficient studies regarding the safety and efficacy of the drug;

- b. The drug was fully and adequately tested, despite knowing that there had been insufficient or inadequate testing of the drug
- c. Prior studies, research, reports and/or testing had been conducted linking the use of the drug to serious prothrombotic reactions, including, but not limited to, adverse cardiovascular events such as pulmonary emboli and vascular events such as deep venous thromboses;
- d. Defendants knew or should have known of reports of increased prothrombotic events associated with the use of the drug;
- e. Defendants knew or should have known of the greatly increased risk of developing pulmonary embolus and/or deep venous thrombosis associated with use of Yasmin; despite this, they were downplaying the risk of the drug.

100. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by defendants, its sales representatives, employees, distributors, agents and/or detail persons.

101. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of Yasmin. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of Yasmin in a timely manner, yet they failed to provide such warning.

102. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest Yasmin to her detriment.

103. As a direct, legal, proximate and producing result of the misrepresentations of Defendants, Plaintiff sustained injuries as set forth above.

### **PRAAYER FOR BELIEF**

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and/or severally, as follows:

- a. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;
- b. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish defendants and deter future similar conduct;
- c. Awarding Plaintiff's reasonable attorney's fees;
- d. Awarding Plaintiff the costs of these proceedings; and
- e. Such other and further relief as this Court deems just and proper.

104. Defendants have repeatedly engaged in the patterns of conduct described herein for the express purpose of maximizing their profits from the sale of Yasmin, at the expense of the health and safety of the public, including Plaintiff.

105. Defendants' acts were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiff and all others taking Yasmin. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and punitive damages in an amount appropriate to punish Defendants and deter similar conduct in the future.

**DEMAND FOR JURY TRIAL**

Pursuant to FRCP 39 (c), Plaintiff demands a trial by struck jury on all issues.

Dated this 9<sup>th</sup> day of December, 2009.



H. Gregory Harp, State Bar ID (HAR299)  
ENVIRONMENTAL LITIGATION GROUP, P.C.  
3529 Seventh Avenue South  
Birmingham, Alabama 35222  
205.328.9200 (Telephone)  
205.328.9456 (Facsimile)  
[għarph@elglaw.com](mailto:għarph@elglaw.com) (Email)

Of Counsel for the Plaintiff